

IN THE CLAIMS

Claims 1-30 (Canceled)

31. (Currently amended) A method for a systemic treatment of migraine and migraine headache, nausea and vomiting, associated with chemotherapy, radiotherapy, surgery, pregnancy, pre-menstrual syndrom (PMS), menstruation or menopause, by delivering an anti-migraine or anti-nausea drug into a systemic circulation with an aid of an intravaginal delivery device, said method comprising steps:

a) preparing an intravaginal delivery device incorporated or coated with a mucoadhesive composition comprising from about ~~0.001~~ 10 to about 500 ~~3000~~ mg per day of the anti-migraine or anti-nausea drug, or a combination of said anti-migraine and anti-nausea drug,

wherein said anti-migraine drug is selected from the group consisting of ergotamine, dihydroergotamine, ergostine, butalbital, ~~phenobarbital, acetaminophen, diclofenac sodium, ketoprofen, ketorolac, ibuprofen, piroxicam, naproxen, acetylsalicylic acid, flurbiprofen, tolfenamic acid, butorphanol, meperidine, methadone,~~ sumatriptan, naratriptan, razatriptan, zolmitriptan, almotriptan, eletriptan, ~~dexamethasone, hydrocortisone,~~ isometheptene, chlorpromazine, ~~diazepam, droperidol,~~ valproic acid, ~~gabapentin, topiramate~~ and divalproex sodium, and

wherein said antinausea drug is selected from the group consisting of metoclopramide, prochlorperazine, domperidone,

ondansetron, tropisetron, dolasetron, nabilone, dronabinol, levonantradol, aprepitant, cyclizine, promethazine, and a combination thereof,

said composition further comprising from about 30 to about 95% of a lipophilic or hydrophilic carrier, from about 0.1 to about 25% of a mucoadhesive agent and from about 5 to about 30% of a non-ionizable sorption promoter; and

b) administering said intravaginal delivery device to a vagina of a female subject in need of such treatment.

32. (Previously presented) The method of claim 31 wherein said intravaginal device is a tampon, tampon-like device, pessary, ring, tablet, capsule, pad, patch, suppository, cup, sponge, strip, foam, film or an intravaginal iontophoretic system.

33. (Previously presented) The method of claim 32 wherein said composition is formulated and incorporated into or coated onto said device as a cream, lotion, foam, film, suppository, tablet, microparticle, nanoparticle, capsule, capsule containing microparticles, emulsion, liposomal suspension fluid, a bioadhesive system or microemulsion.

34. (Previously presented) The method of claim 33 wherein said mucoadhesive agent is hydroxypropyl methylcellulose, a cellulose derivative, a natural gum, alginate or pectin, present in from about 1.5 to about 15%, by weight, wherein said sorption promoter is ethoxydiglycol, polyethylene glycol caprylic/capric

glycerides, a glycol derivative with oleic acid esters of propylene glycol and glycerol or interesterified stone oil present in from about 2 to about 30%, by weight, wherein the lipophilic carrier is a saturated mono-, di- or triglyceride of fatty acids having carbon chain of from 8 to 18 carbons, or a mixture thereof, present from about 30 to about 95%, by weight, wherein the hydrophilic carrier is a polyethylene glycol (PEG) having a molecular weight between about 200 and 8000, or a derivative or mixture thereof, PEG 6000/PEG 1500, PEG 6000/PEG 1500/PEG 400, or PEG 6000/PEG 400, or PEG 8000/PEG 1500, each present from about 30 to about 95%, by weight.

35. (Previously presented) The method of claim 34 wherein said mucoadhesive agent is hydroxypropyl methylcellulose present in from about 1.5 to about 15%, by weight, wherein said sorption promoter is ethoxydiglycol present in from about 15%, by weight, wherein said lipophilic carrier is the saturated mono-, di- or triglyceride of fatty acids having carbon chain of from 8 to 18 carbons and a mixture thereof, present from about 65 to about 70%, by weight, and wherein said hydrophilic carrier is PEG6000/PEG1500 or PEG 6000/PEG400 mixture, present in about 75%, by weight.

36. (Currently amended) The method of claim 35 wherein said treatment of migraine comprises administration of said intravaginal device further comprising said composition comprising from about 15 to about 300 mg/day of ergotamine, ~~from about 100 to about 500 mg/day of diclofenac sodium,~~ from about 20

to 500 mg/day of sumatriptan, from about 10 to about 420 mg/day of zolmitriptan, from about 20-500 mg/day of almotriptan, or from about 10 to about 350 mg/day of naratriptan, and wherein said treatment of nausea comprises administration of a composition comprising from about 20 to 120 mg/dose of metoclopramide, from about 25 to 150 mg/dose prochlorperazine, from about 30 to 210 mg/dose of ondansetron, from about 10 to 50 mg/day of dronabinol or from about 12 to about 80 mg/dose of promethazine.

37. (Previously presented) The method of claim 36 wherein said device is administered to the female subject at the onset of or during the migraine, migraine headache, nausea, vomiting, menstruation or pre-menstrual syndrom.

38. (Previously presented) The method of claim 36 wherein said device is the foam incorporated with said composition.

39. (Previously presented) The method of claim 36 wherein said device is the foam coated with said composition.

40. (Previously presented) The method of claim 36 wherein the device is the tampon incorporated with said composition.

41. (Previously presented) The method of claim 36 wherein the device is the tampon coated with said composition.

42. (Previously presented) The method of claim 36 wherein the device is the tampon and said composition is formulated as a

Attorney Dkt.: 3715.12-1  
Serial No.: 10/600,849

PATENT

foam or film and said tampon is either incorporated or coated with said foam or film.

43. (Withdrawn) The method of claim 36 wherein said antimigraine drug is sumatriptan.

44. (Withdrawn) The method of claim 36 wherein said antimigraine drug is almotriptan.

45. (Previously presented) The method of claim 36 wherein said antimigraine drug is naratriptan.